REMARKS

Claims 1, 3-4, 9, 11, 13-14, 34-36, and 42 are currently amended and new claims 45-47 added. Claims 1-20 and 34-47 appear in the application for the Examiner's consideration. The amendments to claims 1, 3, 13-14, 35, and 42 and new claims 45-47 are supported by the original claims and the specification, for example page 5, lines, 20-24. No new matter has been added. As no new matter has been introduced, Applicant respectfully requests that the amendments and new claims be entered at this time.

The Examiner states that claim 1 is not enabling by the specification as required under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner states that, while the specification recites the peptide sequence with Lys at position 44, Leu at position 45, and Trp at position 47 as a crucial scaffold element representing VH/VL interface in the exemplary library (page 5, lines 22-24), the elected claim (10) species Phe-Pro-Trip-Gly-Asp-Leu-Ala-Glu-Lys does not contain these residues.

Applicant respectfully requests reconsideration of this statement. Applicant wishes to point out that claim 10 is directed to the randomized CDR3 sequence between residues 95-100C and not to the VH/VL interfacing framework at positions 44, 45, and 47. Because the sequence Phe-Pro-Trip-Gly-Asp-Leu-Ala-Glu-Lys pertains to the residues 95-100C, and not the residues 44-47, the sequence does not contain the residues Lys, Leu, and Trp.

Applicant has now amended independent claims 1, 3, 13, 14, 35, and 42 to include residues 44, 45 and 47 of the VH/VL interface due to the importance of these residues. Support for this amendment can be found in the specification at page 5, lines 18-20. New claims 45-46 further clarify the residue at position 44 (see page 5, lines 22-24).

In view of the foregoing, Applicant respectfully requests that this rejection be withdrawn.

Claims 1-4, 9-10, 19, 34-36, and 40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A. The Examiner states that the maximum limit included by the term "at least one charge" in claim 1 is unclear. In response, the term "at least one charge" has been deleted from the above amended claim 1, and a more detailed structural description is provided. By specifying residues at positions 44, 45, and 47, claim 1 now provides more structure for the

polypeptide (see specification at page 17, lines 24-32). Applicant also notes that, in Figure 1 and Sequence ID NO:2, the Lys at the 45th position is what is referred to in the specification and the amended claims as position no. 44 according to the nomenclature used in the art (see, for example, Figure 1 on page 688 of the attached article Reiter et al. 1999, in which there is a position 35a after position 35). Because the nomenclature used in the art dictates that position 35a follow position 35, positions 44, 45, and 47 in the application refer to the 45th (Lys), 46th (Leu), and 48th (Trp) positions in the sequence.

B. The Examiner states that the term "unique" in claims 3 and 35 is indefinite as to its scope. In response, the term is deleted and the claims are amended by including the provision regarding residues 44, 45 and 47 of SEQ ID NO:2 of the VH/VL interface. The amended claims 3 and 35 provide a greater structural definition for the VH/VL interface.

The Examiner also notes that claim 1 does not recite a randomized CDR3. However, claim 1 does not recite a randomized CDR3 because the randomized CDR3 defines the library and not the individual polypeptides of claim 1. In contrast to claim 1, the polypeptide of claim 3 is further defined by the structure of randomized CDR3, in addition to having the residues Lys at position 44, Leu at position 45, and Trp at position 47.

C. The Examiner states that claims 4 and 36, which recite *E. coli* as the host organism for production of the selected polypeptide, are indefinite as they relate to a method step and broaden the base claim with the recited *E. coli*. Applicant respectfully requests reconsideration of this statement. Since production of polypeptide in a specific host only limits the possibilities, claims 4 and 36 further define the polypeptide described in claims 3 and 35, as one skilled in the art would readily understand. Moreover, claims 4 and 36 have been rewritten as above to elucidate that the claims pertain to the definition of the polypeptide.

D. The Examiner states that claims 10 and 40, reciting the sequence between residues 95 and 100C, are confusing as to the recited 95 and 100C. According to the Kabat nomenclature (see reference in the specification at page 11, lines 17-19), there are positions 100A, 100B, and 100C after position 100 and, therefore, the peptide comprising residues 95-100C includes nine amino acids. Similar to the explanation given in paragraph A above, the nomenclature dictates that position no. 95 come at the 99th position of the sequence and position no. 100C come at the 107th position. Hence, the residues at the 99th through 107th positions of SEQ ID NO:2 form the sequence Phe-Pro-Thr-Gly-Asp-Leu-Ala-Glu-Lys, identified as positions 95-100C according to the Kabat nomenclature.

E. The Examiner states that the basis of the term "substantially" in claim 34, referring to the monomeric form of the polypeptide, is not defined in the specification. In response, the term "substantially" is replaced with the term "predominantly" as recited in the specification (page 12 line 24, page 15 line 24, and page 25 line 11).

Claims 1-4, 9-10, 19, 34-36, and 40 are rejected under 35 U.S.C. § 102(f) for not being invented by Applicant. The Examiner bases this rejection on an article written by Reiter et al. (JMB, 1999). However, this article of Reiter et al. was published on July 16, 1999, which is after the Applicant's priority date of November 11, 1998. The Reiter article cited by the Examiner is indeed a scientific description of the invention that was invented solely by the present inventor. The other authors were added to reflect their general scientific contribution and not their contribution to the inventiveness of the subject matter. Applicant notes that the term "we" on page 26 of the specification was used because the technical experiments were performed with the aid of other technicians and service providers, who, however, did not contribute to the inventive step of the invention and are therefore not inventors as defined by the MPEP. Furthermore, Applicant submits herewith a certified copy of Israeli priority application 127127, establishing the priority date as November 11, 1998. In view of these facts, Applicant requests that this rejection be withdrawn.

Accordingly, at least claims 1-4, 9, 10, 19, 34-36, and 40 are in condition for allowance. Claims 5-8, 11, 12, 37-41, and 45-47 are also allowable since they depend from allowed claims. In addition, claims 13-18, 20, and 42-44 should be allowed as these claims are directed to peptides derived from the randomized sequence of the CDR3 region of the polypeptides that were allowed in the other claims. For these reasons, all current claims should be allowed.

It is also respectfully submitted that the restriction requirement should be modified to include other polypeptides in the scope of the Examiner's search because no relevant prior art was uncovered. The Reiter et al. article is not prior art because it is dated later than the priority date of this application. The other polypeptides are recited in the previously withdrawn dependent claims.

In view of the foregoing, it is believed that the entire application is now in condition for allowance, early notification of such would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues in order to expedite the eventual allowance of the claims.

Please contact the undersigned if there are have any questions regarding this application.

Respectfully submitted,

Date 10/21/03

30,256

Allan A. Fanucci (Reg. No.)

WINSTON & STRAWN LLP
CUSTOMER NO. 28765
(212) 294-3311